In The Matter Of:

Deane Berg v.

Johnson & Johnson, et al.

Daniel W. Cramer, M.D., Sc.D.

September 17, 2012

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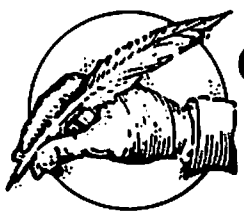

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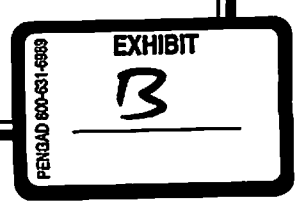

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Q. -- what do you mean by that?
A. Well, what I mean by that is this figure I provided in part of my report did not include a paper by Morman and did not include a paper by Rosenberg. Those were added.
Q. Okay. And is that part of the other disks that we have?
A. It's all in that.
Q. Alright.
A. It's all in the one I just gave you.
Q. In terms of the questions regarding medications -- okay. I'm looking at what I consider Version 5 --
A. Yes.
Q. -- of your form -- are the names of the medications actually collected, or is it a categorical question?
A. No. The names are collected.
Q. Okay. So, when you did your reanalysis as part of these new tables we got today, and you have epileptic -- epileptic and anti-seizure medications, are you identifying specific medications or a class of medications?
A. Yes. I'm sorry. I will bring up our list

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of medications under that category and show you which ones I -- I checked off as being epileptic medications.
Q. So what you did is you went through, and you selected or put in your new analysis that you provided us here today certain -- you selected certain medications to include and certain not to include?
A. We -- we have the -- the category that we included that under was under anti-seizure medications and tranquilizers.
Q. Uh-huh. Just --
A. I provided the names of all of those, and I gave you both the tranquilizers and the seizure medications.
Q. And is that as part of this or --
A. Yes. It's -- that's a -- it's the variable on there and relates to --
Q. Well, the heading I saw, I thought, just said tranquilizers or --
A. Seizure medications.
Q. -- seizure medications.
A. But we -- we split the two. I can -- you are able to combine the two from the data I gave you.

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Q. Okay. What I'm asking, though, is, do we know what tranquilizers or what seizure medications?
A. Those were aggregated. Those were aggregated.
Q. Okay. So we don't have a name; we don't know whether it's --
A. I can.
Q. -- Tegretol versus whatever?
A. Yeah. We don't -- no. Those were aggregated.
Q. Okay.
A. They are often too few to -- in one category to single out as one --
Q. Okay.
A. -- one --
Q. And is this CD that you just gave me as part of Exhibit 10, is that going to -- are you going to show the computations of the programming and how --
A. Those were in.
Q. -- they are put in?
A. That's a no.
Q. What -- what's your definition of recall bias?

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A. Well, it would be a bias that leads one group of patients or, probably -- it's usually spoken of in respect to the cases, cases being more likely to recall an exposure than controls.
Q. Uh-huh. Can recall bias, if it exists, affect a study? What I mean by a study, I mean, affect the results.
A. I would assume it can, yes.
Q. Okay. Are there -- are -- are there ways, methods that epidemiologists use to address potential recall bias?
A. Yes. I mean, yes. There's certain ways you could address that. I mean, commonly is there -- you look for a general trend for cases to be reporting an exposure more frequently than another.
Q. Uh-huh.
A. If you're talking about a particular drug or category of drugs, would cases -- did cases report more of the -- all of these categories of drugs or just one specific.
Q. Uh-huh. Are there ways to go back temporally? Are there certain mechanisms that epidemiologists use where you go back and -- and reask the questions or ask them at different times?

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association.
Q. How many times have they looked at it?
A. I think -- believe, they looked at it in 2000 and looked at it again in 2004.
Q. Okay. The 2007 paper entitled "Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc," you're the lead author?
A. Yes.
Q. Dr. Godleski is on this one, too.
A. Yes.
Q. Okay. This is basically a case report, right?
A. It is.
Q. And this was published, it looks like, in 2007, American College of Obstetricians and Gynecologists. I think, most people call it --
A. Right.
Q. -- ACOG.
A. ACOG. That's right.
Q. Okay.
A. It's The Green Journal. "Obstetrics and Gynecology" is the journal.
Q. I'll be happy to show this to you after I

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read it. I've only got one copy of it, but on Page 500, it says, (as read) "Also, we are not claiming that a causal relationship between ovarian cancer and talc use is proven for this case or in general." Is that what you thought in 2007?
A. That's what you have to say in a case report, that a case report by itself does not establish causality.
Q. Don't you use the word, in general?
A. The -- I think, that's -- yes. I did use the word, in general.
Q. You say in this case and in general.
A. This case report by itself does not establish causality in general.
Q. Okay. Do you know when you submitted this? If it's published in 2007, how much earlier than 2007 would you have submitted this?
A. I think, it's, probably -- it -- it says on there when it was submitted, I believe.
Q. Can you help me.
A. Let's see.
(Attorney hands document to witness.)
A. (Witness reviews document) Well, I'm sure it was probably -- it was about at -- at least a year.

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Q. Well, that's why I was asking about how long it takes.
A. Yeah.
Q. So you might have submitted this sometime in 2006?
A. Yes. I -- I -- I think so.
Q. And by this time in 2000 -- certainly, by the time it was published in 2007, you had started to think about your MUC-1 theory, had you not?
A. Yes.
Q. Okay. I'm going bounce around your report a little more just to make sure I -- I understand a couple of things.
You said that you came up with a one in a trillion chance. That chance is unlikely an explanation for the 1.31 relative risk that you reported?
A. Yes.
Q. You remember -- you know what I'm talking about?
A. Yes. Uh-huh.
Q. How do you calculate that?
A. Well, you -- the meta-analysis gives you a Z value, how far you -- how far you deviate from the

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standard distribution.
Q. Uh-huh.
A. That Z value was, I believe, about 7.6. Now, it's difficult to sometimes find a table which tells you Z value -- the equivalent P value for a Z value that high.
Q. Uh-huh.
A. Some you look up, and it says infinity. The best we could come up with was a trillion.
Q. Okay. So you were spotting this infinity and just going to a trillion?
A. No. I think -- I think, we eventually did find that that was about the right P value for 7.6 Z value.
Q. How does that chance change, if there's some unknown risk that, maybe, we don't know today that are consistently unaccounted for?
A. That chance merely addresses the issue of whether or not just by chance the meta -- all of the studies that consisted that gave you data to the meta-analysis were totally off the track.
Q. Okay.
A. So that's that P -- that's -- that's that Z value and P value.

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Q. Bless you.
Okay. And, based on your -- the brand information that went into Versions 3, four -- or three and a half, four, and five?
A. Yes.
MR. MAYWHORT: Excuse me.
Q. Okay. Why do you mention in your report that ovarian cancer rates increased 78 to 98? I just don't understand the relevance of it.
A. I'm sorry. What?
Q. You mentioned in your report that the rates of ovarian cancer increased between 78 and, I think, 98.
A. Where is that? I'm sorry.
Q. I don't know. It's in your report. Page 7, I think.
MR. WILLIAMS: You going to be okay, Bill?
MR. MAYWHORT: Yeah. Thank you.
A. (Witness reviews document) You know, I don't know see that. I -- I point out around...
Q. Alright.
A. I --
Q. Maybe, I dreamed it up.
A. I don't -- I don't see it. I don't think

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I've -- I don't think that's true.
Q. Okay.
A. I believe, Huncharek or Muscat mentioned that there was some increase over that time period.
Q. Alright. I think, you mentioned in the paper -- paper -- your report that a relative risk of two is -- is sometimes considered a benchmark for associations.
A. Yes. I'm paraphrasing what many others have said, particularly --
Q. Well, why -- what is that? Why is a relative risk of two considered something of a benchmark?
A. You know, I -- I don't know why that is. I mean, certain -- I suppose it relates to etiologic fractions, again --
Q. Uh-huh.
A. -- that, when you -- when you do that relative risk minus one over relative risk, you get to one-half. That's two, and then you can say, well, more than 50 percent chance here. But there's nothing -- no -- no famous epidemiologists have ever said you need a relative risk of two for there to be causal association.

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Q. What about Dr. Cramer; what's your position on it?
A. My position would be that cause -- causality is not determined solely by the strength of the relative risk.
Q. What's -- what's your low-end number? Is there one?
A. There are no -- no low-end number.
Q. That's no low-end number, no.
It all depends -- on any given set of studies, there's really -- you can look at a variety of different factors, as you've explained to me before, and you might say, in this study, I'm not going to say it's causal, unless there's a two, and in another study, you might say, it's causal, because it's -- it's with a lower relative risk.
A. No. You would not go by that, and I use the analogy of data merging from the GWAS studies, genome-wide association studies.
Q. Uh-huh.
A. Here they find snips that are associated with 1.15 or 15 percent increase in risk, which are almost, certainly, to be causal, because they have been duplicated in thousands of cases and thousands

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of controls.
Q. Uh-huh.
A. So there is no lower bound --
Q. Okay.
A. -- for that relative risk.
Q. Talking about those studies reminded me of a couple of things.
In terms of BRCA mutations, what -- what percentage of ovarian cancer cases, if there's a number that you recognize, are attributed to BRCA mutations?
A. Well, we talked about around 10 or 11 percent in a -- in a non-Jewish population. It's more like 40 percent in a Jewish population.
Q. Okay. So are you saying that 40 percent of the female Jewish population carries those genes?
A. No. 2 percent of the Jewish population --
Q. Okay.
A. -- carries --
Q. Right.
A. -- the founder mutations.
40 percent of women who come to a diagnosis of ovarian cancer and are Jewish will be found to have one of those common mutations.

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A. When I was contacted by Mr. Allen {vertatim}, I was asked can you give us your opinion about the causality of talc in general and in the case of Ms. Berg. It is my opinion that there is a causal relationship between talc and ovarian cancer, and it pertains in the case of Ms. Berg. It is my opinion.
Q. Okay. Outside of yourself and Dr. Godleski, are you aware of any medical professional who has ever placed in writing his or her opinion that perineal use of talc is causal with respect to ovarian cancer?
A. I would have to go through those reports, but you recall the IARC declared it a possible carcinogen.
Q. A 2B, in other words --
A. Yes.
Q. -- as opposed to a number one classification?
A. Yes.
Q. Okay. Let me restate the question with regard to the name of any medical professional or any other professional in the fields of epidemiology or biostatistics.

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If you can, sitting here today, cite us to any written article that anyone in the U.S. or Europe has ever prepared that states that there is a causal relationship between the perineal use of talc and ovarian cancer.
A. You know, I know the literature pretty well, but I can't speak for every paper that's been written on talc and ovarian cancer.
I've -- certainly, Dr. Nasir said this fits with her inflammatory pathway. Can I say there is someone who has come right out and said this is the cause? I don't -- I don't -- I can't give you that name right now.
Q. So, at least as far as sitting here today, Doctor, you regard yourself and Dr. Godleski as being the first medical professionals ever to state this causal relationship in writing?
A. I -- as -- as far as I'm aware.
Q. Okay. Toward the end of Mr. Williams' examination, you discussed somewhat the effect of tubal ligations upon production of MUC-1 antibodies.
A. Right.
Q. And, I believe, that your testimony -- correct me if I'm wrong -- was that there is some

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evidence that tubal ligation increases the MUC-1 antibodies.
A. Right.
Q. In your opinion, is that increase in MUC-1 level -- MUC-1 antibodies -- antibodies to a degree that is greater or less than the use of talc in terms of its effect upon or -- or any relationship or association with --
A. Well, it's going in different directions --
Q. Yes, sir.
A. -- obviously.
I would have no way to balance that out, but it does raise the point is that we have to view the risk for ovarian cancer as a compilation of many things that happen to the woman, not just whether she had mumps, not just whether she used talc, but how did these factors all come together in her case.
Clearly, the mumps was not protective in her case. Clearly, the tubal ligation was not protective in her case, but it's -- it's -- it just illustrates the complexity of the whole business but that we will have to eventually look at this broader picture of what was the totality of exposures.
And, in Ms. Berg's case, the 10,000

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applications of talc, I believe, that played a major role in the cause of her disease.
Q. Would her long-term use of antidepressants have played a role in her -- her disease?
A. I know she had long-term use of seizure medications. I don't know whether she had long-term use of antidepressants.
Q. I misspoke.
A. I don't believe they played a role, and I gave you some -- I gave data here to suggest that seizure medications do not increase the risk for ovarian cancer, and there -- and there's disagreement in the literature on whether psychotropics increase the risk for ovarian cancer.
Probably, the best study is from Seattle based upon pharmacy records, and they found no association with -- with the antidepressants.
Q. Would Ms. Berg's long-term use of dairy products have been a cause -- a cause --
A. I don't believe so.
Q. -- of her ovarian cancer?
A. I don't believe so.
Q. Why not?
A. Because, as I -- we indicated, the case